

Regimen Monograph

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A - Regimen Name

ABEMTMXF Regimen

Abemaciclib-Tamoxifen

Disease Site Breast

Intent Adjuvant

Regimen Category **Evidence-informed :**

Regimen is considered appropriate as part of the standard care of patients; meaningfully improves outcomes (survival, quality of life), tolerability or costs compared to alternatives (recommended by the Disease Site Team and national consensus body e.g. pan-Canadian Oncology Drug Review, pCODR). Recommendation is based on an appropriately conducted phase III clinical trial relevant to the Canadian context OR (where phase III trials are not feasible) an appropriately sized phase II trial. Regimens where one or more drugs are not approved by Health Canada for any indication will be identified under Rationale and Use.

This **Regimen Abstract** is an **abbreviated** version of a Regimen Monograph and contains only top level information on usage, dosing, schedule, cycle length and special notes (if available). Information in regimen abstracts is accurate to the extent of the ST-QBP regimen master listings, and has not undergone the full review process of a regimen monograph. Full regimen monographs will be published for each ST-QBP regimen as they are developed.

Rationale and Uses For adjuvant treatment of HR+, HER2-, node-positive early breast cancer, in patients who are at high risk of disease recurrence

Refer to EAP for abemaciclib funding details.

Supplementary Public Funding [abemaciclib](#)
Exceptional Access Program (abemaciclib - For the adjuvant treatment, in

combination with endocrine therapy, of adult patients with HR-positive, HER2-negative, node-positive early breast cancer at high risk of disease recurrence based on clinicopathological features and a Ki-67 score of at least 20%.)
[\(EAP Website\)](#)

[tamoxifen](#)

ODB - General Benefit (tamoxifen) ([ODB Formulary](#))

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B - Drug Regimen

abemaciclib	150 mg	PO	BID
tamoxifen	20 mg	PO	Daily

Note: For pre- or perimenopausal women, and men, consider treatment along with gonadotropin releasing hormone (GnRH) agonists according to local clinical practice.

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C - Cycle Frequency

CONTINUOUS TREATMENT

Up to a total of 2 years of treatment, unless disease progression or unacceptable toxicity occurs. Tamoxifen monotherapy may continue.

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D - Premedication and Supportive Measures

Antiemetic Regimen: Minimal – No routine prophylaxis; PRN recommended

Screen for hepatitis B virus in all cancer patients starting systemic treatment. Refer to the [hepatitis B virus screening and management](#) guideline.

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J - Administrative Information

Outpatient prescription for home administration

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K - References

Abemaciclib drug monograph, Ontario Health (Cancer Care Ontario).

CADTH reimbursement review: Abemaciclib (Adjuvant treatment of hormone receptor–positive, human epidermal growth factor receptor 2–negative early breast cancer), December 2022.

Johnston SRD, Harbeck N, Hegg R. Abemaciclib combined With endocrine therapy for the adjuvant treatment of HR+, HER2-, node-positive, high-risk, early breast cancer (monarchE). J Clin Oncol. 2020 Dec 1;38(34):3987-98.

Tamoxifen drug monograph, Ontario Health (Cancer Care Ontario).

October 2023 Modified Rationale/uses section; added abemaciclib funding information

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M - Disclaimer

Regimen Abstracts

A Regimen Abstract is an abbreviated version of a Regimen Monograph and contains only top level information on usage, dosing, schedule, cycle length and special notes (if available). It is intended for healthcare providers and is to be used for informational purposes only. It is not intended to constitute or be a substitute for medical advice, and all uses of the Regimen Abstract are subject to clinical judgment. Such information is provided on an “as-is” basis, without any representation, warranty, or condition, whether express, or implied, statutory or otherwise, as to the information’s quality, accuracy, currency, completeness, or reliability, and Cancer Care Ontario disclaims all liability for the use of this information, and for any claims, actions, demands or suits that arise from such use.

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Regimen Monographs

Refer to the [New Drug Funding Program](#) or [Ontario Public Drug Programs](#) websites for the most up-to-date public

funding information.

The information set out in the drug monographs, regimen monographs, appendices and symptom management information (for health professionals) contained in the Drug Formulary (the "Formulary") is intended for healthcare providers and is to be used for informational purposes only. The information is not intended to cover all possible uses, directions, precautions, drug interactions or adverse effects of a particular drug, nor should it be construed to indicate that use of a particular drug is safe, appropriate or effective for a given condition. The information in the Formulary is not intended to constitute or be a substitute for medical advice and should not be relied upon in any such regard. All uses of the Formulary are subject to clinical judgment and actual prescribing patterns may not follow the information provided in the Formulary.

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Some Formulary documents, such as the medication information sheets, regimen information sheets and symptom management information (for patients), are intended for patients. Patients should always consult with their healthcare provider if they have questions regarding any information set out in the Formulary documents.

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